IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDTRONIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; MEDTRONIC LOGISTICS, LLC; MEDTRONIC USA, INC., Plaintiffs, v. AXONICS, INC., Defendant.	C.A. No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Medtronic, Inc., Medtronic Puerto Rico Operations Co. ("MPROC"), Medtronic Logistics, LLC ("Medtronic Logistics"), and Medtronic USA, Inc. ("MDT USA") (individually and collectively, "Medtronic" or "Plaintiffs") bring this Complaint against Defendant Axonics, Inc., alleging as follows:

THE PARTIES

1. Plaintiff Medtronic, Inc. is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

2. Plaintiff MPROC is a Cayman Islands corporation having its principal place of business located at Ceiba Norte Industrial Park, 50 Road 31, Km. 24.4, Juncos, Puerto Rico 00777-3869.

3. Plaintiff Medtronic Logistics is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

4. Plaintiff MDT USA is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

5. Defendant Axonics, Inc. ("Axonics" or "Defendant") is a Delaware corporation having its principal place of business located at 26 Technology Dr., Irvine, CA 92618.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement under 35 U.S.C. § 271 *et seq*.

7. This Court has subject matter jurisdiction over this action under the laws of the United States, 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has general personal jurisdiction over Axonics because Axonics is engaged in substantial and not isolated activity and is incorporated within this judicial district. This Court has specific jurisdiction over Axonics because Axonics has committed acts giving rise to this action and has established more than minimum contacts within this judicial district, such that the exercise of jurisdiction over Axonics in this Court would not offend traditional notions of fair play and substantial justice.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)–(c) and 1400(b) because Axonics is incorporated and has committed acts of patent infringement within this judicial district.

FACTUAL BACKGROUND

Medtronic's Background

10. Medtronic is one of the world's largest medical technology, services, and solutions companies with the focus of alleviating pain, restoring health, and extending life for millions of people around the world.

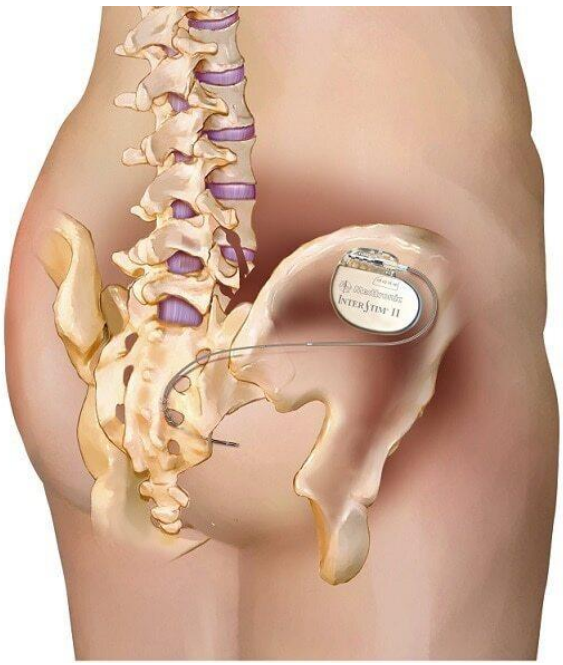
11. Among its areas of specialty, Medtronic provides products and services in the area of pelvic health. Pelvic floor disorders adversely affect the health and quality of life of millions of people. Pelvic floor disorders include urinary control disorders such as overactive bladder, fecal control disorders, sexual dysfunction, and pelvic pain. Pelvic floor disorders can be treated with a variety of therapeutic options, including surgical intervention.

12. Medtronic is the pioneer and leading provider of neuromodulation solutions for bladder and bowel control issues. Medtronic offers three products that operate similarly to help control symptoms of overactive bladder, non-obstructive urinary retention, and chronic fecal incontinence through direct modulation of the nerve activity: InterStim X and InterStim II, which

are recharge-free sacral neuromodulation (SNM) systems, and the InterStim Micro, which is a rechargeable SNM system. Collectively, these products will be referred to in this Complaint as the Medtronic InterStim system.

13. The Medtronic InterStim system electrically stimulates the sacral nerves, which aims to normalize neural communication between the bladder and brain, and between the bowel and brain.

14. Generally, implantation of InterStim therapy involves surgically implanting a stimulation lead near the sacral nerves. The stimulation lead is a very small, insulated electrical conductor with electrical stimulation contacts on the distal end placed near the sacral nerves, and an electrical connector on the opposite proximal end of the lead. The stimulation lead is connected to an implantable neurostimulator that delivers small electrical pulses for stimulation of the sacral nerves. InterStim therapy can improve the condition of a pelvic floor disorder and allow a patient to lead a full life. The image below shows an example of the implantation of an



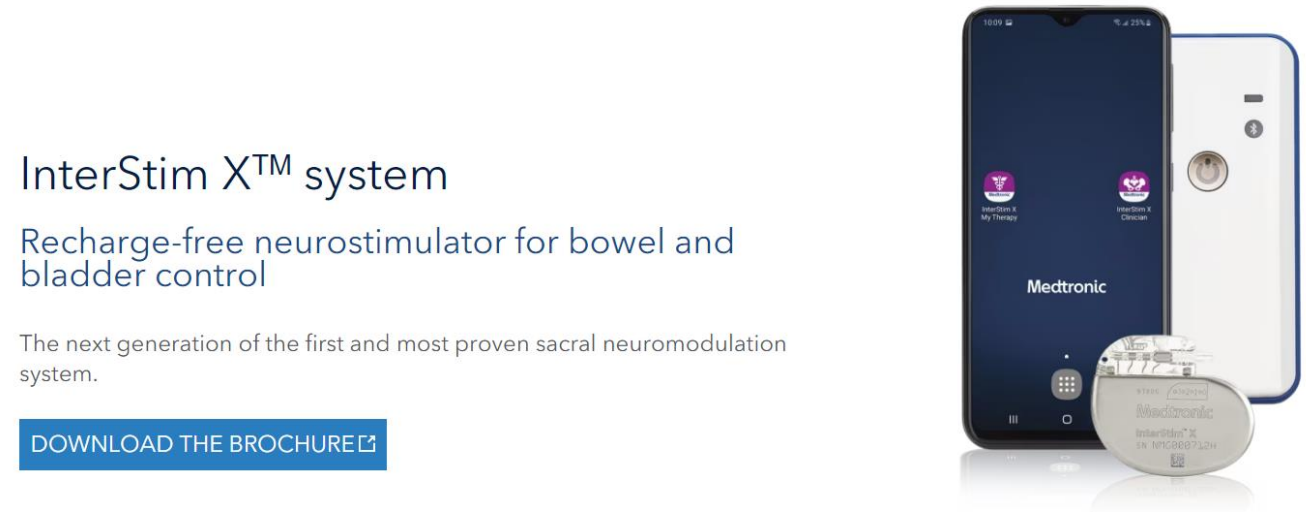
InterStim device.[1]

[1] https://www.medtronic.com/nl-nl/patienten/behandelingen-en-therapieen/neurostimulator-blaas-darmcontroleproblemen/ingreep/ingreep-wat-kunt-u-verwachten.html.

15. The Medtronic InterStim system includes a clinician programmer for the implantable stimulation device that allows a physician or clinician to program the device and adjust its settings. It also includes a patient programmer that allows the patient to control a limited subset of parameters for the implantable stimulation device to deliver therapy to the patient.

16. The Medtronic InterStim system is also configured to be compatible with magnetic resonance imaging ("MRI") modalities, such that a patient can safely obtain an MRI notwithstanding the implant. Prior to obtaining such an MRI, the patient programmer is configured to indicate whether proceeding with the MRI would be safe for the patient.

17. The images below show an example of the InterStim X system, which includes the InterStim X Model 97800 Neurostimulator, the TM90 Communicator, and the Model HH90 smart programmer with the Clinician App and Patient App.



Accused Products and Activities

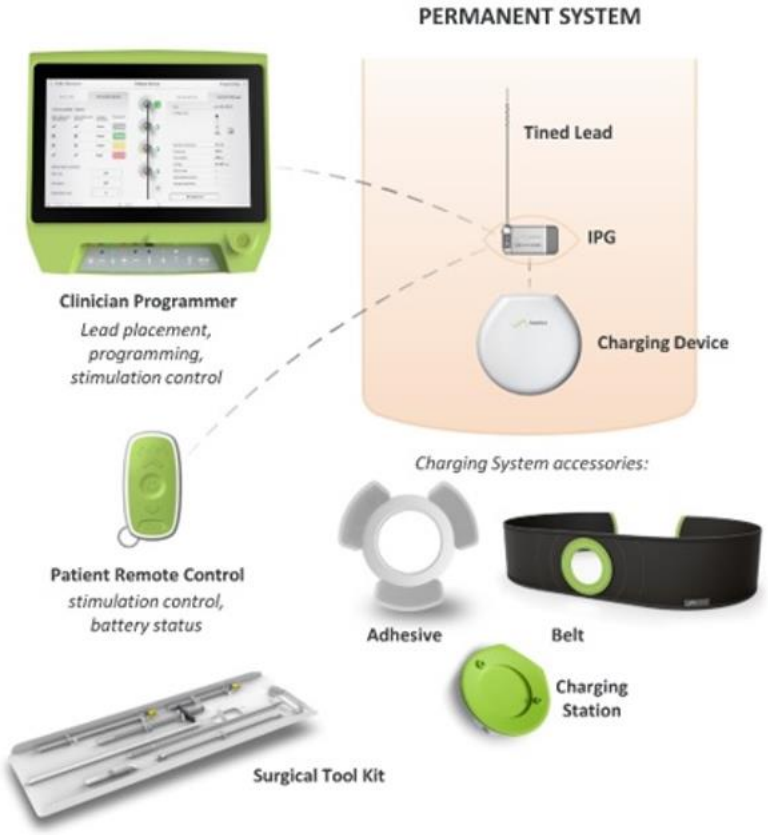
18. Axonics is a medical technology company that provides SNM products.[2] According to Axonics's website, "Axonics aspires to be the global leader in incontinence therapies by providing customer-centric solutions to treat urinary and bowel dysfunction and improve quality of life for patients and their families."[3]

19. Upon information and belief, Axonics's SNM products include medical programmers with printed circuit boards, components thereof, and products and systems for use with the same. The programmers are used in systems to control neurostimulators surgically implanted into a human patient and that deliver small electrical pulses for stimulation of the sacral nerves. Axonics SNM products include the Axonics F15 Recharge-Free SNM System

[2] http://www.axonics.com/hcp/.
[3] *Id.*

(Model 4101), the Axonics R20 Rechargeable SNM System (Model 5101), and the Axonics R15 Rechargeable SNM System (Model 1101). Each system includes various components, such as a neurostimulator, tined lead, charging system (if rechargeable), clinician programmer, and patient remove control. Collectively, these products will be referred to as the Accused Products in this Complaint.

20. Axonics announced that the first commercial implants of the Axonics R15 System in the United States were planned to take place on the week of October 28, 2019.[4] The image below from the FDA website shows an example of components for one Accused Product, the Axonics SNM system using the Axonics R15 Rechargeable SNM System.[5]



21. According to the FDA Summary of Safety and Effectiveness Data for Axonics's

[4] Axonics® Announces First Commercial U.S. Patient Implanted with its Sacral Neuromodulation System, *available at*: https://ir.axonics.com/news-releases/news-release-details/axonicsr-announces-first-commercial-us-patient-implanted-its/.
[5] *See* https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006B.pdf at 6.

R15 System, "[t]he components of the Axonics System are similar to those used in . . . the Medtronic® InterStim® Therapy System."[6] According to the same regulatory filing, the Axonics R15 System is similar in design, technology, performance, indication for use, output characteristics, and patient population to the Medtronic InterStim system.[7]

22. Axonics has designed its SNM products such that the implantation procedure is the same as that of the existing Medtronic InterStim system.[8] For example, Axonics analyzed Medtronic's product in detail before making the Axonics R15 System.[9] The image below shows a graphic of the Axonics R15 system implanted.[10]

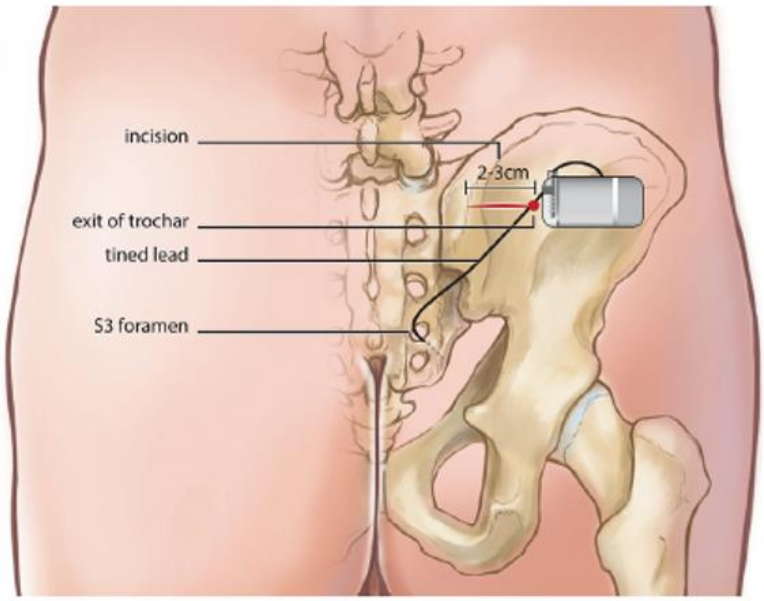


FIGURE 11 Placement of the Axonics IPG

[6] *Id.* at p. 3–5.
[7] *Id*. at p. 25.
[8] *See, e.g.*, Joshua A. Cohn, Casey G. Kowalik, Melissa R. Kaufman, W. Stuart Reynolds, Douglas F. Milam & Roger R. Dmochowski (2017), "Evaluation of the axonics modulation technologies sacral neuromodulation system for the treatment of urinary and fecal dysfunction," *Expert Review of Medical Devices* (hereinafter "Cohn 2017"), at 4; *available at*: https://doi.org/10.1080/17434440.2017.1268913.
[9] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/.
[10] *See* Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," at 7, Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); available at: https://doi.org/10.1002/nau.23482.

23. Axonics provides instructions to its customers and healthcare professionals for using the Axonics SNM products at least in its product manuals, in documents relating to regulatory filings, and by and through its representatives and consultants.[11]

THE PATENTS-IN-SUIT

24. On April 29, 2014, the United States Patent and Trademark Office (PTO) issued United States Patent No. 8,712,540 ("the '540 patent"), titled "Patient Programmer with Automated MRI Compatibility Verification for Active Implantable Medical Device." The '540 patent lists the following individuals as inventors: Hrishikesh Gadagkar, James Zimmerman, James M. Olsen, Robyn L. Jagler, Timothy R. Abraham, and Jeffrey R. Dixon. The '540 patent is valid and enforceable. A copy of the '540 patent is attached as Exhibit A.

25. Medtronic, Inc. is the owner of the '540 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreement, the exclusive license under the '540 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreement, the exclusive sub-license under the '540 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreement, the exclusive sub-license under the '540 patent to offer for sale and sell. As a result of these agreements and Medtronic's ownership of the '540 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of the '540 patent.

26. On November 3, 2015, the PTO issued United States Patent No. 9,174,059 ("the '059 patent"), titled "Patient Programmer with Automated MRI Compatibility Verification for Active Implantable Medical Device." The '059 patent lists the following individuals as

[11] *See, e.g.*, Axonics Sacral Neuromodulation System – Neurostimulator Implant Manual ("FDA Physician Manual") at 56–64; available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006c.pdf; see also Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit), at 13–21; available at: https://www.axonics.com/images/110-0128-001rA_Tined_Lead_Manual,_Gemini,_FI_US_English_efile.pdf.

inventors: Hrishikesh Gadagkar, James Zimmerman, James M. Olsen, Robyn L. Jagler, Timothy R. Abraham, and Jeffrey R. Dixon. The ’059 patent is valid and enforceable. A copy of the ’059 patent is attached as Exhibit B.

27. Medtronic, Inc. is the owner of the ’059 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreement, the exclusive license under the ’059 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreement, the exclusive sub-license under the ’059 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreement, the exclusive sub-license under the ’059 patent to offer for sale and sell. As a result of these agreements and Medtronic’s ownership of the ’059 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of the ’059 patent.

COUNT I

(Infringement of U.S. Patent No. 8,712,540)

28. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–27 of this Complaint.

29. Upon information and belief, Axonics makes, uses, imports, offers for sale, and/or sells in the United States the Accused Products and systems and components for use with the same that directly infringe at least claims 1–5, 7, 11, 12, 14, 15, 17, 18, and 20 of the ’540 Patent, pursuant to 35 U.S.C. § 271(a).

30. By way of non-limiting example, Exhibits C–E, submitted herewith, are claim charts showing how the Accused Products directly infringe each asserted independent claim of the ’540 Patent.

31. Upon information and belief, Axonics currently actively induces and has induced infringement of the ’540 Patent pursuant to 35 U.S.C. § 271(b) through, among other things, the making, using, importing, offering for sale, and/or selling in the United States the Accused Products and systems and components for use with the same to customers and end users with the

specific intent that the Accused Products be used in an infringing manner.

32. Upon information and belief, Axonics has had knowledge of the ’540 Patent and knowledge that the use of the Accused Products and systems and components for use with the same by customers and end users according to the instructions included with the Accused Products infringes the asserted claims of the ’540 Patent since at least the filing of this Complaint.

33. For example, the instructions included with Axonics’s Patient Remote Control depict a programmer configured to adjust the stimulation level of an implantable neurostimulator to relieve the symptoms of urinary and fecal dysfunction. *See* Exhibit F at 2. The system is further configured to “check[] if system is ready for full-body MRI without requiring an office visit.” *Id*. Additionally, the system is configured to enable a clinician to control the therapy parameters available to a patient. *See* Exhibit G at 21.

34. As detailed in the attached exemplary claim charts, Exhibits C–E, the use of the Accused Products constitutes direct infringement of at least the asserted independent claims of the ’540 Patent. The supply of those products therefore induces customers and end users to use the Accused Products in an infringing manner. As indicated above, Axonics has encouraged customers and end users to use the Accused Products in an infringing manner by providing instructions to customers and end users to use the Accused Products in an infringing manner.

35. Pursuant to 35 U.S.C. § 271(c), on information and belief, Axonics makes, uses, imports, offers for sale, and/or sells in the United States the Accused Products and systems and components for use with same that contribute to the infringement of the asserted claims of the ’540 Patent.

36. Upon information and belief, Axonics has committed, and continues to commit, affirmative acts that cause infringement of the asserted claims of the ’540 patent with knowledge or willful blindness of the ’540 patent, and knowledge or willful blindness that the induced acts constitute infringement of the asserted claims of the ’540 patent. For example, Axonics induces such acts of infringement (i) by its affirmative actions of intentionally providing products that,

when used in their normal and customary way as desired and intended by Axonics, infringe the asserted claims of the '540 patent, and (ii) by providing instructions for using its products in a manner or configuration that infringes the asserted claims of the '540 patent.

37. Upon information and belief, Axonics provides the Accused Products to others, such as customers, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, care providers, sales representatives, suppliers, distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or sell the Accused Products in a manner that directly infringes the asserted claims of the '540 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Accused Products as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as customers, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the accused products in a manner that directly infringes the asserted claims of the '540 patent.

38. Moreover, upon information and belief, Axonics has hired a U.S. sales team that includes former members of Medtronic's sales team who received training from Medtronic, which consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics's U.S. sales team, who are fully trained regarding Axonics's product, have been and will be "strategically mapped to and located where current high volume implanters are practicing in the United States."[12] Upon information and belief, the sales team has been responsible for and continues to be responsible for "supporting cases in the [operating room], interacting with patients and programming the implanted [Axonics] device."[13] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics's customers regarding the use of the Accused Products in the United States in a manner that directly infringes the asserted claims of the '540 patent.

[12] *See* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call (May 8, 2019, 8:30PM GMT).
[13] *Id.*

39. Upon information and belief, Axonics has contributed to, and continues to contribute to, the infringement of the ’540 patent by others by knowingly providing the Accused Products that constitute a material part of the asserted claims of the ’540 patent, with knowledge that the Accused Products are to be especially made or especially adapted for use in infringement of the ’540 patent. Upon information and belief, Axonics also committed, and continues to commit, contributory infringement by, *inter alia*, knowingly offering for sale and selling the Accused Products, which have no substantial non-infringing uses, and which constitute a material part of the asserted claims of the ’540 patent.

40. As discussed above, the Accused Products are designed and sold to be used only for implanting their components in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Accused Products in a way that infringes at least one claim of the ’540 patent, and they do not contemplate any non-infringing uses.

41. Upon information and belief, Axonics has had knowledge of the ’540 Patent and that use of the Accused Products infringes the asserted claims of the ’540 Patent, and learned of this during at least one or more of the following events: in the course of its due diligence and freedom to operate analyses, including the “many initial months [spent] examining patents and IP issues;”[14] as part of the due diligence investigation performed for SEC filings; and from the filing of this Complaint. Contemporaneously with the filing of this Complaint, Medtronic provided Axonics with a copy of the Complaint and non-confidential exhibits to the Complaint. As a result, Axonics received notice of the ’540 Patent and the infringement at issue no later than the filing of the Complaint. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of the ’540 patent.

42. Axonics knows that its Accused Products are specially made or specially adapted

[14] https://www.sec.gov/Archives/edgar/data/1603756/000160375619000054/axnx-110519xex991.htm.

for use in the infringement of the asserted claims of the ’540 Patent. The Accused Products and components thereof are not staple articles or commodities of commerce suitable for substantial non-infringing use, and the Accused Products are material parts of the invention of the ’540 Patent. Accordingly, Axonics is contributing to the direct infringement of the asserted claims of the ’540 Patent when the Accused Products and components thereof are made, imported, assembled, sold, and/or used.

43. Upon information and belief, Axonics’s infringement of the ’540 patent has been and continues to be willful.

44. Upon information and belief, Axonics knew of the ’540 patent or was willfully blind to its existence.

45. Axonics’s infringement of the ’540 patent has been without permission, consent, authorization, or license from Medtronic.

46. As a result of Axonics’s infringement, Medtronic has suffered and will continue to suffer damages in an amount to be proved at trial. In addition, Axonics’s infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

COUNT II

(Infringement of U.S. Patent No. 9,174,059)

47. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–46 of this Complaint.

48. On information and belief, Axonics makes, uses, imports, offers for sale, and/or sells in the United States the Accused Products and systems and components for use with the same that directly infringe at least claims 1–5, 7, 11, 12, 14, 15, 17, 18, and 20 of the ’059 Patent, pursuant to 35 U.S.C. § 271(a).

49. By way of non-limiting example, Exhibits H–J, submitted herewith, are claim charts showing how the Accused Products directly infringe each asserted independent claim of the ’059 Patent.

50. Upon information and belief, Axonics currently actively induces and has induced infringement of the ’059 Patent pursuant to 35 U.S.C. § 271(b) through, among other things, the making, using, importing, offering for sale, and/or selling in the United States the Accused Products and systems and components for use with the same to customers and end users with the specific intent that the Accused Products be used in an infringing manner.

51. Upon information and belief, Axonics has had knowledge of the ’059 Patent and knowledge that the use of the Accused Products and systems and components for use with the same by customers and end users according to the instructions included with the Accused Products infringes the asserted claims of the ’059 Patent since at least the filing of this Complaint.

52. For example, the instructions included with Axonics’s Patient Remote Control depict a programmer configured to adjust the stimulation level of an implantable neurostimulator to relieve the symptoms of urinary and fecal dysfunction. *See* Exhibit F at 2. The system is further configured to “check[] if system is ready for full-body MRI without requiring an office visit.” *Id*. Additionally, the system is configured to enable a clinician to control the therapy parameters available to a patient. *See* Exhibit G at 21.

53. As detailed in the attached exemplary claim charts, Exhibits H–J, the use of the Accused Products constitutes direct infringement of at least the asserted independent claims of the ’059 Patent. The supply of those products therefore induces customers and end users to use the Accused Products in an infringing manner. As indicated above, Axonics has encouraged customers and end users to use the Accused Products in an infringing manner by providing instructions to customers and end users to use the Accused Products in an infringing manner.

54. Pursuant to 35 U.S.C. § 271(c), on information and belief, Axonics makes, uses, imports, offers for sale, and/or sells in the United States the Accused Products and systems and components for use with same that contribute to the infringement of the asserted claims of the ’059 Patent.

55. Upon information and belief, Axonics has committed, and continues to commit,

affirmative acts that cause infringement of the asserted claims of the ’059 patent with knowledge or willful blindness of the ’059 patent, and knowledge or willful blindness that the induced acts constitute infringement of the asserted claims of the ’059 patent. For example, Axonics induces such acts of infringement (i) by its affirmative actions of intentionally providing products that, when used in their normal and customary way as desired and intended by Axonics, infringe the asserted claims of the ’059 patent, and (ii) by providing instructions for using its products in a manner or configuration that infringes the asserted claims of the ’059 patent.

56. Upon information and belief, Axonics provides the Accused Products to others, such as customers, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, care providers, sales representatives, suppliers, distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or sell the Accused Products in a manner that directly infringes the asserted claims of the ’059 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Accused Products as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as customers, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the accused products in a manner that directly infringes the asserted claims of the ’059 patent.

57. Moreover, upon information and belief, Axonics has hired a U.S. sales team that includes former members of Medtronic’s sales team who received training from Medtronic, which consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics’s U.S. sales team, who are fully trained regarding Axonics’s product, have been and will be “strategically mapped to and located where current high volume implanters are practicing in the United States.”[15] Upon information and belief, the sales team has been responsible for and continues to be responsible for “supporting cases in the [operating room], interacting with patients and programming the

[15] *See* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call (May 8, 2019, 8:30PM GMT).

implanted [Axonics] device."[16] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics's customers regarding the use of the Accused Products in the United States in a manner that directly infringes the asserted claims of the '059 patent.

58. Upon information and belief, Axonics has contributed to, and continues to contribute to, the infringement of the '059 patent by others by knowingly providing the Accused Products that constitutes a material part of the asserted claims of the '059 patent, with knowledge that the Accused Products are to be especially made or especially adapted for use in infringement of the '059 patent. Upon information and belief, Axonics also committed, and continues to commit contributory infringement by, *inter alia*, knowingly offering for sale and selling the Accused Products, which have no substantial non-infringing uses, and which constitute a material part of the asserted claims of the '059 patent.

59. As discussed above, the Accused Products are designed and sold to be used only for implanting their components in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Accused Products in a way that infringes at least one claim of the '059 patent, and they do not contemplate any non-infringing uses.

60. Upon information and belief, Axonics has had knowledge of the '059 Patent and that use of the Accused Products infringes the asserted claims of the '059 Patent, and learned of this during at least one or more of the following events: in the course of its due diligence and freedom to operate analyses, including the "many initial months [spent] examining patents and IP issues;"[17] as part of the due diligence investigation performed for SEC filings; and from the filing of this Complaint. Contemporaneously with the filing of this Complaint, Medtronic provided Axonics with a copy of the Complaint and non-confidential exhibits to the Complaint. As a result, Axonics received notice of the '059 Patent and the infringement at issue no later than

[16] *Id*.
[17] https://www.sec.gov/Archives/edgar/data/1603756/000160375619000054/axnx-110519xex991.htm.

the filing of the Complaint. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of the ’059 patent.

61. Axonics knows that its Accused Products are specially made or specially adapted for use in the infringement of the asserted claims of the ’059 Patent. The Accused Products and components thereof are not staple articles or commodities of commerce suitable for substantial non-infringing use, and the Accused Products are material parts of the invention of the ’059 Patent. Accordingly, Axonics is contributing to the direct infringement of the Asserted Claims of the ’059 Patent when the Accused Products and components thereof are imported, assembled, sold, and/or used.

62. Upon information and belief, Axonics’s infringement of the ’059 patent has been and continues to be willful.

63. Upon information and belief, Axonics knew of the ’059 patent or was willfully blind to its existence.

64. Axonics’s infringement of the ’059 patent has been without permission, consent, authorization, or license of Medtronic.

65. As a result of Axonics’s infringement, Medtronic has suffered and will continue to suffer damages in an amount to be proved at trial. In addition, Axonics’s infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

A. Adjudge that Axonics has infringed and is infringing one or more claims of each of the above patents-in-suit, directly and/or indirectly, literally, and/or under the doctrine of equivalents;

B. Award damages sufficient to compensate Plaintiffs for Axonics’s infringement under 35 U.S.C. § 284, including an award of treble damages for willful infringement;

C. Find this case exceptional under 35 U.S.C. § 285, and award Medtronic its reasonable attorneys' fees;

D. Enjoin Axonics, and all persons in concert or participation with it, from directly or indirectly infringing one or more claims of each of the above patents-in-suit, directly and/or indirectly, literally, and/or under the doctrine of equivalents;

E. Award Plaintiffs their costs and expenses incurred in this action;

F. Award Plaintiffs pre-judgment and post-judgment interest; and,

G. Grant Plaintiffs such further relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all claims so triable.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Ste. 200
Wilmington, DE 19801
302-472-7300
dgattuso@hegh.law

Attorneys for Plaintiffs Medtronic, Inc. Medtronic Puerto Rico Operations Co., Medtronic Logistics, LLC and Medtronic USA, Inc.

OF COUNSEL:

WINSTON & STRAWN LLP
George C. Lombardi
35 W. Wacker Drive
Chicago, IL 60601-9703
glombardi@winston.com

Nimalka Wickramasekera
333 South Grand Avenue, 38th Floor
Los Angeles, CA 90071-1543
213-615-1819
nwickramasekera@winston.com

Brian E. Ferguson
Robert T. Vlasis III
1901 L Street NW
Washington, DC 20036
202-282-5000
bferguson@winston.com
rvlasis@winston.com

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